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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,295	SCHAEBITZ ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-104* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, 101-102 are drawn to methods comprising administering of a hematopoietic factor selected from the group consisting of GMCSF, a GMCSF derivative, GCSF, a GCSF derivative and combinations thereof, classified in class 514, subclass 2.

II. Claims 20-21, 90-100, 103-104 are drawn to methods comprising administering polynucleotides encoding a hematopoetic factor selected from the group consisting of GMCSF, a GMCSF derivative, GCSF, a GCSF derivative and combinations thereof, classified in class 514, subclass 44.

III. Claims 22-34 are drawn to methods of administering neural stem cells that have been contacted with a hematopoetic factor selected from the group consisting of GMCSF, a GMCSF derivative, GCSF, a GCSF derivative and combinations thereof, classified in class 424, subclass 93.1.

IV. Claims 35-37, are drawn to screening methods comprising contacting neuronal cells with said compound that binds to GCSF receptor and measuring an increase in STAT activation relative to controls, classification dependent upon structure of the recited “compound”.

V. Claim 38, drawn to a compound identified by the screening method of Group IV, classification dependent upon structure of the recited "compound".

VI. Claims 39-51 are drawn to methods of treatment comprising administering the compound of Group V, classification dependent upon structure of the recited "compound".

VII. Claims 52-54, 77-78, 80-89 are drawn to screening methods comprising contacting neuronal cells with a compound that binds to GMCF receptor comprising contacting neuronal cells with said compound and measuring an increase in STAT gene activation relative to controls, classification dependent upon structure of the recited "compound".

VIII. Claim 55, 79 is drawn to a compound identified by the screening method of Group VII, classification dependent upon structure of the recited "compound".

IX. Claims 56-64 are drawn to methods of treatment comprising administering the compound of Group VIII, classification dependent upon structure of the recited "compound".

X. Claim 65 is drawn to methods of screening for agonists of GCSF receptor, comprising contacting a neural cell with said compound, measuring the neuroprotective effect with the compound relative to the effect of GCSF, classification dependent upon structure of the recited "compound".

XI. Claim 66 is drawn to a compound identified by the screening method of Group X, classified in classification dependent upon structure of the recited "compound".

XII. Claims 67-76 are drawn to methods of treatment comprising administering the compound of Group XI, classification dependent upon structure of the recited "compound".

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-IV, VI-VII, IX-X, XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group I is drawn to protein therapy, whereas Group II is drawn to gene therapy; Group III is drawn to neural stem cell therapy; Groups IV, VII and X are drawn to screening methods comprising measuring protein activation (IV), gene activation (VII) and neuroprotection (X); Groups VI, IX and XII are drawn to treatment methods comprising administration of different compound identified by different screening methods. The methods in each of the different Groups are distinct with different goals and method steps, and because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions I-III and V, VIII and XI are unrelated. In the instant case, the products of Groups V, VIII and XI have yet to be identified, and would not necessarily be usable

in methods of administering proteins (I), genes (II) or stem cells (III). A different search would have to be carried out for each of the different products with regard to the mode of administration, (see MPEP § 808.02), thus restriction for examination purposes as indicated is proper.

Inventions II and III-IV, VI-VII, IX-X, XII are unrelated. In the instant case, Group II is drawn to gene therapy; Group III is drawn to neural stem cell therapy; Groups IV, VII and X are drawn to screening methods comprising measuring protein activation (IV), gene activation (VII) and neuroprotection (X); Groups VI, IX and XII are drawn to treatment methods comprising administration of different compound identified by different screening methods. The methods in each of the different Groups are distinct with different goals and method steps, and because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions III and IV, VI-VII, IX-X, XII are all unrelated. In the instant case, Group III is drawn to neural stem cell therapy; Groups IV, VII and X are drawn to screening methods comprising measuring protein activation (IV), gene activation (VII) and neuroprotection (X); Groups VI, IX and XII are drawn to treatment methods comprising administration of different compound identified by different screening methods. The methods in each of the different Groups are distinct with different goals and method steps, and because these inventions are independent or distinct for the reasons given

above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions IV and VII and X are each unrelated to one another. In the instant case, although all three methods comprise screening for compounds, each of the different methods have different steps and endpoint measurements. Groups IV measures protein activation, Group VII measures gene activation and Group X measures neuroprotection (X). Protein activation is not measured using the same methods or equipment as gene activation, and endpoints of neuroprotection encompass many types of experiments, for instance, oxidative stress determination, functional and structural imaging of cells and/or toxicity testing. Products that change protein activity may or may not cause a change in gene expression, and changes in gene expression do not always translate into changes in protein levels. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions IV, V and VI are related as process of making and process of using the product. Likewise, inventions VII, VIII and IX and X, XI and XII are related as process of making and process of using the product. The use as claimed in Groups VI, IX or XII cannot be practiced with materially different products than those recited in Groups V, VIII or XI, respectively. Since the product is not allowable (i.e., it has not yet

been identified, thus cannot be allowed), restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Inventions IV and VIII, IX, XII are unrelated. Group IV is drawn to screening methods comprising measuring protein activation, Group VIII is drawn compounds identified by measuring gene activation; Group IX is drawn to treatment methods comprising administering compounds identified by gene activation assays and Group XII is drawn to treatment methods comprising administering compounds identified by neuroprotection assays.

Inventions V and VIII and XI are each unrelated to one another. In the instant case, although all three comprise products, each of the products were identified using different screening, each with different endpoint measurements. Products that change protein activity may or may not cause a change in gene expression, and changes in gene expression do not always translate into changes in protein levels. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions V and VII, IX, X and XII are unrelated. In the instant case, Group V is drawn to a product identified by a screening method measuring protein activation,

whereas Group VII is a screening method measuring gene activation and Group IX is a drawn to a treatment method comprising administering a compound identified by measuring gene activation. Group X is drawn to screening methods measuring neuroprotection endpoints and Group XII is drawn to treatment methods comprising administering a compound identified by neuroprotection assays. Products that activate proteins may not necessarily be neuroprotective, and likewise, a product that is neuroprotective does not necessarily affect protein activation. Thus, because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions VI and VII-XII are unrelated. In the instant case, Group VI is drawn to treatment methods comprising administering a compound identified by screening for protein activation, whereas, Group VII is drawn to screening methods measuring gene activation, Group VIII is drawn to compounds identified by screening for gene activation, Group IX is drawn to treatment methods comprising administering a compound identified by screening for gene activation, Group X is drawn to screening methods measuring neuroprotective endpoints, Group XI is drawn to compounds identified by screening for neuroprotective endpoints and Group XII is drawn to treatment methods comprising administering compounds identified by screening for neuroprotective endpoints. Products that activate protein may or may not also activate gene expression; genes are sometimes up-regulated with no effect upon the protein. In

addition, products that are neuroprotective do not necessarily activate protein and gene expression. In a case where changes in protein activation or gene expression might be harmful, such a product would not be neuroprotective. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Inventions VII and X-XII are unrelated. In the instant case, Group VII is drawn to screening methods measuring gene activation, Group VIII is drawn to compounds identified by screening for gene activation, whereas Group X is drawn to screening methods measuring neuroprotective endpoints; Group XI is drawn to compounds identified by screening for neuroprotective endpoints and Group XII is drawn to treatment methods comprising administering compounds identified by screening for neuroprotective endpoints. Products that are neuroprotective do not necessarily activate gene expression. In a case where changes in gene expression might be harmful, such a product would not be neuroprotective. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

Christina Borgeest, Ph.D.

ELIZABETH KEMMERER
PRIMARY EXAMINER